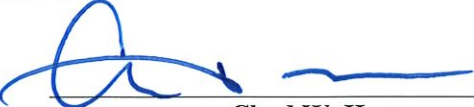
	OFFICE OF RESEARCH AND SPONSORED PROGRAMS <i>Division of Research Compliance</i>		Institutional Biosafety Committee Standard Operating Procedures	
	Title: Post Approval Monitoring			
Effective Date:		Document Number:		IBC-SOP-006.01
Approval/Date:				
 _____ Chad W. Hargrave Vice President & Chief Research Officer			13 Nov 2024 _____ Date	
REVISION HISTORY				

Purpose:

The objective of post-approval monitoring is to collaborate with researchers to ensure accurate and consistent protocol performance in a supportive and non-disruptive manner. For this reason, post-approval monitoring for researchers at SHSU will entail completing a brief continuing review protocol in Cayuse Hazard Safety (CHS). The aim of continuing review is to furnish the Institutional Biosafety Committee (IBC) with a progress report on the activities of the previous year.

Scope:

Continued IBC oversight of research activities involving hazardous materials is mandated by federal laws, regulations, and policies. This Standard Operating Procedure (SOP) offers detailed guidance for completing Continuing Review in Cayuse Hazard Safety.

Definitions and Abbreviations:

- CHS—Cayuse Hazard Safety, Cayuse’s electronic solution for IBC compliance
- DMR—Designated Member Review, the IBC’s process for expedited review
- IBC—Institutional Biosafety Committee
- PI—Principal Investigator
- PAM—Post Approval Monitoring, monitoring of protocols post-initial approval
- SHSU—Sam Houston State University
- SOP/SOP’s—Standard Operating Procedure(s)

Responsibilities:

It is the duty of the SHSU IBC to ensure that all research activities involving hazardous materials comply with federal regulations, policies, and recommendations. As part of Post Approval Monitoring (PAM), it is the responsibility of the PI to submit continuing reviews for all IBC-approved research at SHSU, regardless of the type of hazardous materials used or procedures conducted and irrespective of funding sources. The PI must submit continuing reviews in a timely manner to update the IBC on their progress and to notify the IBC office of:

1. Studies requiring closure before the end of the 3-year approval period.

2. Studies necessitating the removal of personnel.
3. Studies requiring the addition of personnel (note: an amendment submission will be required in this case).
4. Studies with unreported adverse events (if any) during the year.
5. Any planned changes required for the study.

Procedure:

In CHS, the left-hand menu comprises various sections for alerts regarding a PI's protocols, indicating the status of a protocol within the review process. For instance, each active protocol appears in the Continuing Review alert annually for the first-year review. Upon accessing CHS, click on the alert to identify protocols requiring continuing review. Click on the protocol number to open the submission.

Two Options for Continuing Review:

Withdrawing Protocol Approval:

This option is suitable for closing a protocol when the PI leaves the university or completes the research before the 3-year approval period expires. Select "Withdrawn" from the Status pull-down menu and provide a brief progress report in the designated field.

Continuing Protocol Approval:

Select this option to maintain IBC approval for an additional year or until the approval expiration date. Continuing review serves as an annual update to the IBC and should include the following content, aligning with the CHS Continuing Review form: a) Progress made over the previous year b) Removal of personnel leaving the project c) Description of any adverse events in the previous year d) Documentation of future plans for the project, if applicable.

Method of IBC Continuing Review:

1. All IBC members receive a copy of the completed Continuing Review Form and have access to the corresponding IBC protocol file upon request.
2. Any IBC member may request a full committee review of the Continuing Review Form and the protocol.
3. Utilizing the DMR process, if no full committee review is requested within 48 hours, the IBC Analyst designates at least one qualified member (designated reviewer) to conduct an in-depth review of the protocol.
4. Upon approval by the IBC DMR in CHS, the IBC Office releases the CR approval to the PI via email.

References:

Cayuse Hazard Safety Help Center